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Dr. Lester M. Crawford, D.V.M., Ph.D.
FDA Acting Commissioner
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Crawford,

In following with our correspondence on Serious Adverse Event [SAE] reporting issues over the past few years, I have enclosed herewith the comment I posted on the FDA website in response to the invitation for comments on SAE reporting issues.

Briefly, I emphasized that while virtually all SAE reporting problems are associated with large multicenter clinical trials, as opposed to small or single-center trials (for which current regulations are adequate), an initial goal should be to establish a precise definition of "large multicenter clinical trials" which would then become the subject of appropriate new regulations.

Secondly, it is recognized that the content of many SAE reports that are presently being sent to IRBs do not meet current regulatory requirements (e.g. they omit data on the number of 'similar adverse events'), which underscores the problems that: 1)These reports are not checked for completeness before they are sent to IRBs. 2) Sponsors are not setting the precedent that they can be relied upon to make sure that SAE reports meet regulatory requirements before the reports are sent out. 3) IRBs are not in a position to "police" the SAE reports that they receive which do not meet regulatory requirements.

It appears clear that new regulations designed to deal specifically with the conduct of large multicenter clinical trials are urgently needed to provide for the safety of people who participate in today's most widely-used form of human experimentation.

Sincerely,

R. J. Bjork

Robert Bjork, Jr., MD